For everyone concerned with the issues of pharmacovigilance | UPPSALA REPORTS | October 2010

UR51

100 member countries | the ABC of E2B

Vaccine updates | Travelling in Europe | Introducing RACS

Marie Lindquist
Director
the Uppsala Monitoring Centre

A year has now passed since I took up the post as Director of the UMC. Looking back, it has been a good year for me and the UMC team of now nearly 70 people in our offices here in Uppsala. We have worked hard and tackled many challenges; there have been many developments, small as well as more substantial, that the dedicated UMC team have managed on top of the large bulk of work maintaining and developing our baseline services. Unavoidably there have been a few disappointments, but we have also been able to deliver what we all hope are really useful services and products, and realize new opportunities.

Very soon it is time to pack our bags and set off to a real pharmacovigilance hot-spot – Accra, Ghana – for one of the highlights of the year, the annual meeting of national pharmacovigilance centres, followed by the 2010 International Society of Pharmacovigilance meeting. When in Ghana, I shall be very happy to present our recent achievements, so I won't go into details here, but I would like to mention a few things that give an indication of how the UMC in the past year has responded to needs expressed by the pharmacovigilance community.

The roll out of PaniFlow, the web-based tool for pandemic flu vaccine safety monitoring, is an example of a successful new venture – which we undertook with very short notice. Fortunately, the pandemic did not develop as feared, but the important thing was that we were able to provide a tool which could be used by those who otherwise would have had no realistic means of reporting and recording vaccine adverse events.

I am also delighted about the successful establishment of UMC-A in Accra, Ghana, as the first stage of our global outreach programme to have a major presence outside Sweden. Under the leadership of Alex Dodoo we now have what will be a hub of an African network of professionals who can help and support one another in developing pharmacovigilance on the African continent, take an active part in the WHO Drug Monitoring Programme and contribute to fulfilling the vision of safe use of medicines for patients all over the world.

One reason for celebration is that the WHO Drug Monitoring Programme has reached the impressive membership of 100 (actually, we have just reached 101) fully participating national pharmacovigilance centres. This issue of Uppsala Reports has a feature celebrating this achievement of the Programme. In connection with this memorable landmark I take the opportunity to express my sincere appreciation of Sten Olsson for his tireless enthusiastic efforts over many years to expand the global network. Thank you, Sten!

We have known for a long time that the need for pharmacovigilance education and training is enormous, and that currently there are not anywhere near the resources available to meet those needs, particularly in developing and emerging countries. This notion has been further strengthened by recent surveys done by UMC-A, clearly indicating that training and education is a top priority in Africa. UMC-A has also responded to this challenge by creating a web-based 'Pharmacovigilance Toolkit' with support from the Global Fund and other Global Health Initiatives. The first version of this should be available by the year's end.

As my ambition is to develop the UMC into an organization that has what it takes to respond to future expectations and challenges, development of our capacity to deliver training and education is very high on my agenda. The aim is not for the UMC to solve all the world's problems in this area – at least not immediately! – but to develop education materials that can be used by member countries, and together with WHO and other partners deliver training programmes according to a 'train-the-trainers' approach. A UMC Education and Training section dedicated to the development of our efforts in this area is now being implemented in our Pharmacovigilance Services department, to complement the existing two teams: Reporting, Analysis and Country Support (RACS) and the team responsible for product management of our pharmacovigilance tools (including VigiSearch, VigiFlow and CemFlow). I am also recruiting a manager for the department. If you know of someone who would be interested in taking on this important job, please let me know.

The RACS team is introduced in this issue – there will be more information about our other pharmacovigilance teams in coming numbers of Uppsala Reports.

I am looking forward to meeting meet many old and new colleagues and friends in Ghana, and to learn about your expectations for the years to come!

FEATURES

REGULARS

the UPPSALA MONITORING CENTRE

The WHO Programme

Our global network of pharmacovigilance centres passes an important landmark.

Supporting development

The consultants for pharmacovigilance in Africa meet in Togo.

Reporting, Analysis and Country Support

The team at the centre of the UMC's activities presents itself.

National centre visits

Reports on meetings to support national centres in Europe and other recent conferences.

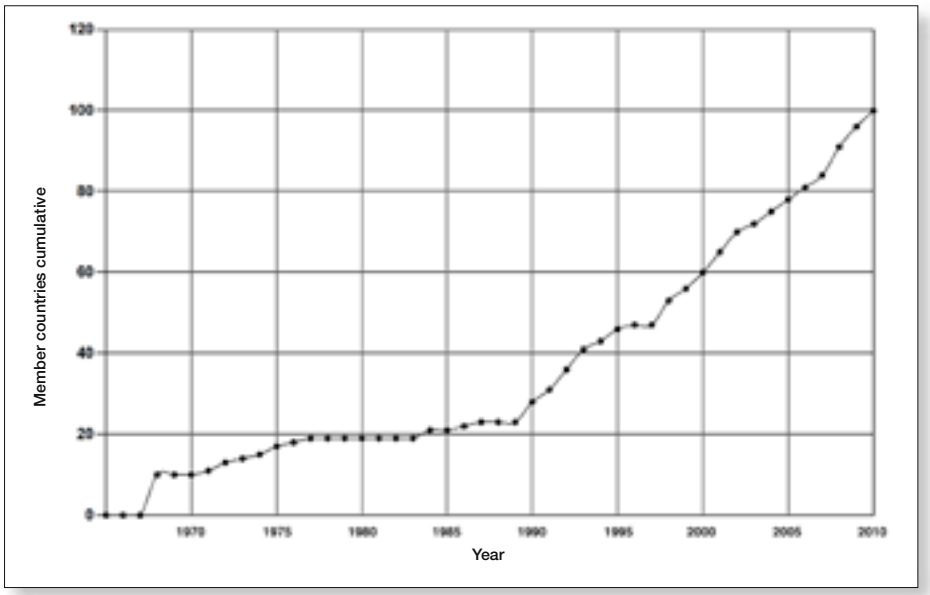
Now 100 full members of the WHO Programme

Sten Olsson

The WHO Programme for International Drug Monitoring recently welcomed its 100th member country. With the accession of Slovenia, there are now 100 countries which are full members in the WHO Programme, all with a commitment to working together and sharing information to optimize the safe use of medical drugs and vaccines for the benefit of patients around the world.

Expanding Programme

The WHO Programme, founded in 1968, initially consisted of western European and north American countries, with New Zealand and Australia. The driving forces behind the creation of the Programme and the activities during the first years were recently described in an article by Jan Venulet and Margaretha Helling-Borda[1]. Over the last 40 years, the Programme has gradually expanded to include countries in all corners of the globe.



Growth in membership of the WHO Programme for International Drug Monitoring, 1968-2010.

Recent progress

The last decade has seen a significant increase in the number of member countries. Earlier this year Zambia, Kenya and DR Congo were admitted to the WHO Programme, following successful submission of adverse reaction reports from their national pharmacovigilance centres to the Uppsala Monitoring Centre. Since the admission of Slovenia, just as we go to press, Côte d'Ivoire has become our 101st member, and Burundi has applied for associate membership – more good news. We hope to introduce the two newest member countries more fully in UR52.

WHO Programme principles

The basis for the WHO Programme for International Drug Monitoring is that all member countries have systems which encourage healthcare professionals, pharmaceutical companies and the public to record and report adverse effects and other medicine-related problems. These individual case safety reports (ICSRs) are assessed locally and may lead to action within the country. Members of the WHO Programme agree to share their ICSRs collected nationally with all other members and in turn have access to all reports collected in other member countries. In technical terms sharing means that ICSRs are submitted to the Uppsala Monitoring Centre in the E2B format (see page 16-17). For many countries this is most easily achieved via the case management system VigiFlow.

Flags in Geneva - the WHO Programme is a truly international network.

Challenges in the future

Clearly there are challenges to the WHO Programme and the way in which it functions and we will return to those in the next *Uppsala Reports*. For the moment we celebrate the new milestone and thank all countries for their support and work to make the WHO Programme what it is today – a truly global partnership of covering all continents, working closely with WHO Headquarters to support patient safety around the world.

[1] Jan Venulet, Margaretha Helling-Borda. WHO's International Drug Monitoring – The Formative Years 1968–1974 *Drug Safety* 2010; 33((7): e1–e23

PAHO/WHO perspectives

José Luis Castro

Pharmacovigilance, from the regulatory perspective, is a function that allows knowing, evaluating, preventing and making decisions and plans in relation with problems generated by the use of medicines. Its importance lies not only in globally addressing new serious adverse medicines reactions but in monitoring unwanted population events related to medicines utilization in the context of the health systems and public health programmes of a particular country, region or settlement.

The plans and activities of the Pan American Health Organization (PAHO) in pharmacovigilance are conducted in agreement with national regulatory authorities of the Americas through a working group of the Pan American Network of Drug Regulatory Harmonization (PANDRH). The PANDRH is an initiative of regulatory authorities and PAHO/WHO with the participation of the pharmaceutical industry, universities and NGOs, intended to harmonize processes and pharmaceutical regulations among countries of the Region of the Americas. It was officially approved by PAHO/WHO directive council in 2000 by resolution CD42/R11[1], and is composed of working groups for specific topics.

PANDRH pharmacovigilance

In 2005 the IV Conference of the Pan American Network of Drug Regulatory Harmonization decided to create the Pharmacovigilance working group[2]. The members are: Colombia (group coordinator), Barbados, Panama, Mexico and Uruguay. A representative from Cuba was appointed by PAHO/WHO and the group includes alternate members and two associated experts: from Argentina and Spain.

At its first meeting in Salvador de Bahia, Brazil in 2006 the group agreed and discussed a diagnostic survey involving 14 countries. This survey provided important elements on availability of human resources, legal framework, infrastructure, reporting or not to Uppsala Monitoring Centre, etc, and identified gaps to develop the group working plan. A similar survey has been recently conducted by the Andean sub region among six countries to update this information. The group mission and objectives are addressed in Figure 1.

Good practice for the Americas

The group has developed the Good Pharmacovigilance practices guidelines for the Americas. The document is intended both for countries with limited activity in the field or those with a higher development of pharmacovigilance to support and encourage their work and to provide guidance for improvement. The Good Pharmacovigilance practices were discussed by experts, submitted to public opinion through the PAHO/WHO web page and finally approved by the V Conference of PANDRH in 2008. The document has been validated and has already been adopted as an official guideline by Argentina, Colombia and the ALBA (Alianza Bolivariana para las Americas) sub regional initiative[3,4].

Figure. 1. Mission and Objectives of the Pharmacovigilance working group of PANDRH.

Mission

To develop and strengthen pharmacovigilance through activities and proposals of harmonized regulatory actions that promote the safe and rational use of medicines as a necessary component of Public Health policies in the Region of the Americas.

Objectives

1. To promote the development and dissemination of knowledge, criteria and methodologies in pharmacovigilance to be used in training activities.
2. To review and develop tools to support harmonization in pharmacovigilance.
3. To design a system that supports the work as a network to improve and strengthen the exchange of communication knowledge and decision making in the area of pharmacovigilance.
4. To foster integration of pharmacovigilance as part of drug policy and public health programs.
5. To promote and disseminate research on pharmacovigilance and evaluation of the impact in public health and patient safety.

In order to strengthen human resources capacity and to foster a pro-active development of pharmacovigilance, during 2010 the group developed a training course with three phases: the first consisting of virtual on-line training, the second implemented as a workshop in Quito, Ecuador last September, and the third phase an intervention to be performed by the participants in their working place. The course, co-ordinated by Cuba, was held via the web-page of the Virtual Campus of Public Health of PAHO/WHO. Seven countries of Latin America are still participating and will finish their tasks by the end of November 2010. After an evaluation of the whole experience and the necessary updates a second version of the training will begin in April 2011.

Focal points

The group has also decided to support the development of the network of focal points for pharmacovigilance in the Americas that is expected to be in place by September 2011. This network will allow countries to share news, knowledge, resources and even criteria. The experience of Caribbean countries with the VigiCarib network (initiated with support from PAHO, WHO and the EU) is a good reference and starting point.

In addition to these steps there is a need to work together, according to each country's resources and special requirements. PAHO/WHO is now cooperating with countries lacking a well-established pharmacovigilance system to build their own plans to strengthen capacities. The bilateral cooperation (eg. Argentina–Paraguay) is one of the additional tasks undertaken to achieve this goal. The exchange of criteria and experiences is also a key element in the dynamic of knowledge and practice. In this regard, professionals of the pharmacovigilance centres have the opportunity for discussing, holding conferences, panels and workshops at the international meeting organized annually in Colombia, and that may soon take a full Regional perspective and commitment. Some also share the global expertise by participating in the National Pharmacovigilance Centres meeting. This took place in Argentina in 2007 and the possibility of holding it in Brazil in the near future would be another very positive and important milestone to add new energy, ideas and stronger collaboration in the Americas.

Moving forward

Challenges may differ from country to country: keeping authorities' commitment, achieving minimum standards, maintaining qualified human resources with population-oriented and pro-active visions and attitudes, a better communication and understanding with other programmes (vaccines, HIV, etc) and the spreading of active monitoring projects (as those related to HIV medicines in Suriname or to Oseltamivir in Argentina and Brazil). All of them require strong and coordinated work, and the pharmacovigilance group, as other groups of PANDRH, is a key instrument to keep moving forward.

1 http://www.paho.org/english/gov/cd/cd42_fr-e.pdf

2 http://www.paho.org/english/ad/ths/ev/pandrh_conclusions_recommendations-ivconference.pdf

3 ANMAT, circular 6008, Nov 20, 2009. http://www.anmat.gov.ar/webanmat/farmaco/GUIA_BPFV.pdf

4 http://www.alianzabolivariana.org/modules.php?name=News&file=article&sid=6815

VigiBase – ICSR reporting update

Cecilia Biriell

Statistics on reporting to the UMC Individual Case Safety Report (ICSR) database, VigiBase, are presented twice yearly in Uppsala Reports and on the UMC website.

Continued increase in reporting

The last time these statistics were presented, in UR49 last April, the total of 5 million case reports in VigiBase™ had just been passed. The fast increase in the volume of cases submitted to VigiBase has continued and the total number of reports has now passed 5.6 million. The next milestone – of 6 million case reports – will probably be reached within this year.

It took 18 months to receive the last million reports, but it will probably take less than a year to achieve the next milestone.

Figure 1. Growth of WHO database

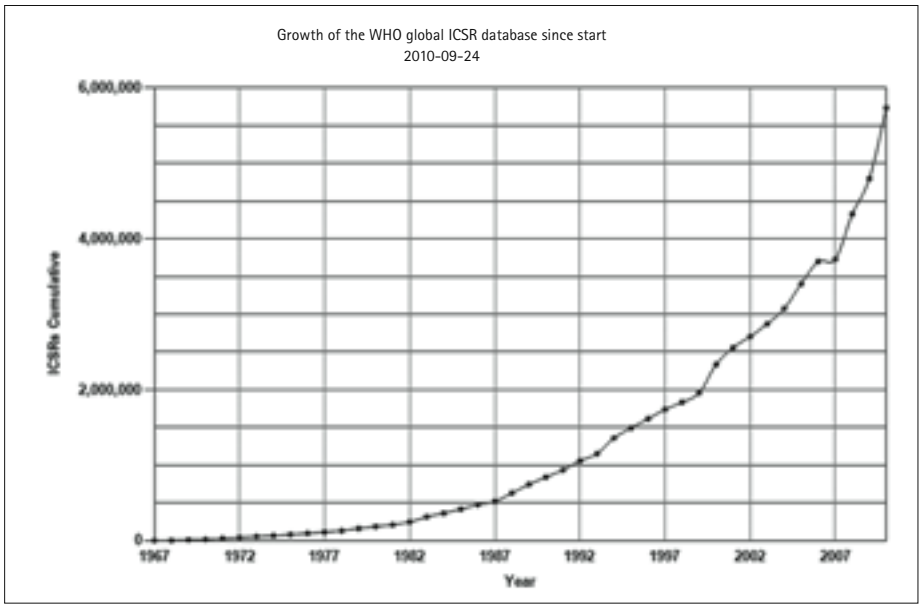
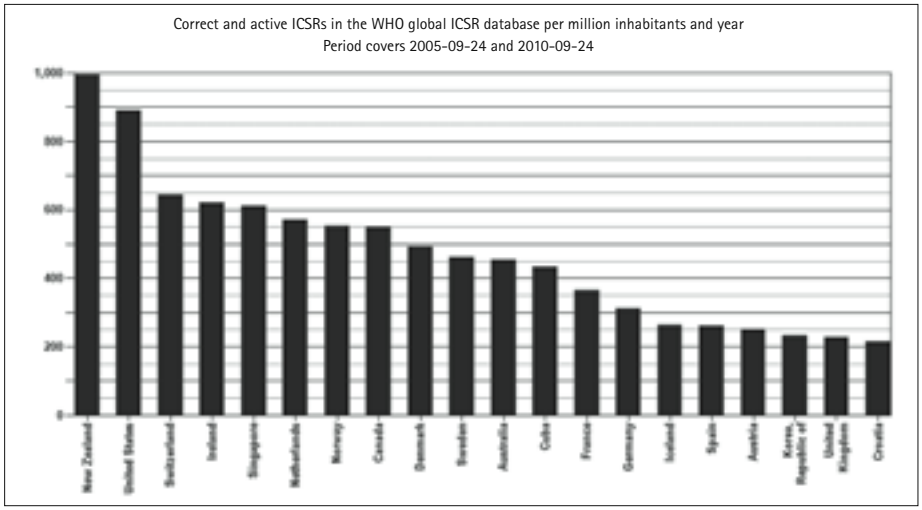


Figure 2. Country reporting rates over a 5-year period



Vaccine-related reporting restarted

The main reason for the fast increase in the number of ICSRs in VigiBase is that after a gap of several years, reporting of vaccine-related data from the US FDA has now recommenced. A backlog of several hundred thousand reports has been sent to UMC. The processing of all of these reports has started, but will take several weeks. UMC is very happy about the reestablishment of cooperation with CBER (Centre for Biologics Evaluation and Research) at FDA. Details of the vaccine-related ADR reporting are given on page 14 of this edition of *Uppsala Reports.*

More countries using recommended format

In UR49 UMC could report that an increasing number of countries are now using the internationally recommended format for ICSR submissions, ICH-E2B. This trend has continued over the last six months. As of September 2010, 64 out of 99 countries were reporting in the ICH-E2B format (which includes those using VigiFlow™). The increase is mainly due to the fact that several countries (mainly in Africa) have now decided, after a trial period, to use the ICSR management system VigiFlow, which is set up according to the international standard for reporting.

Cumulative reporting

The average yearly increase in number of ICSRs over the five years 2004 - 2008 was approximately 350,000. The figure increased in 2009 to 516,000 and is 1 September 2010 already 817,000 ICSRs, as mentioned above, to a great extent due to the submission of backlogs of vaccine reports. As of 1 September 2010, the total number of active ICSRs in VigiBase was 5,639,596.

The proportion of reports in VigiBase from different countries stays mainly the same as before, with USA accounting for almost half of the database. With the addition of US vaccine reports this figure will probably increase even further.

Submission frequency

WHO Programme members are encouraged to submit ICSRs to the UMC regularly, preferably once a month, but at least every quarter. UMC now is in a position to put in more resources into co-operation with reporting countries to overcome technical problems that may prevent national centres submitting ICSRs regularly.

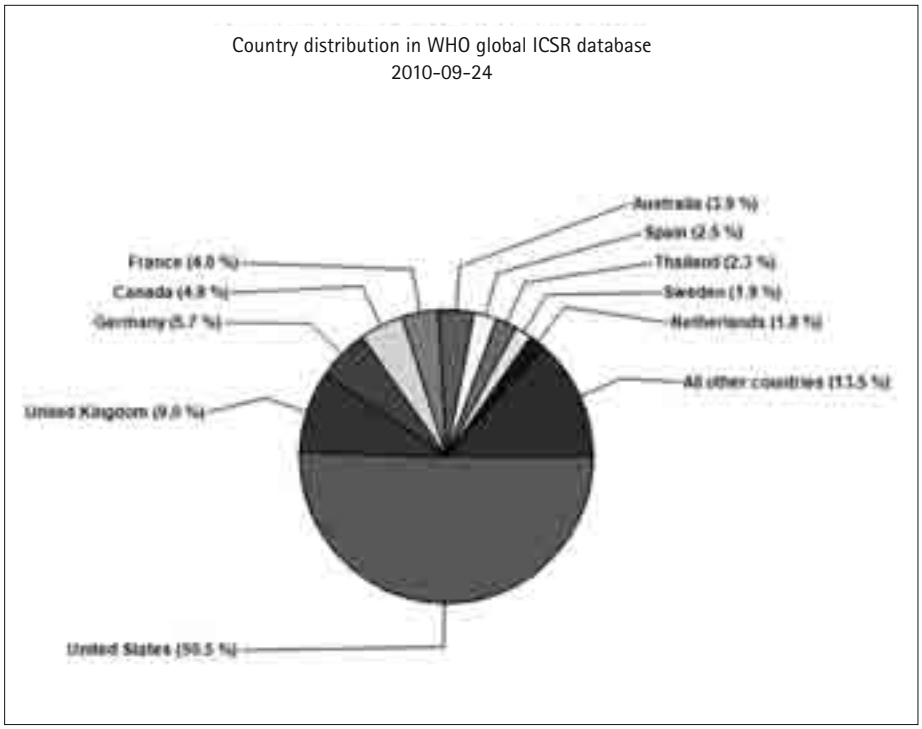
58 countries have submitted reports over the last three months. This is slightly less than in March when the last statistics were presented. Maybe this was due to summer holidays in many member countries? Let's hope countries get back to normal routines shortly.

14 countries have not reported any ICSRs over the last 12 months, which is a slight increase since last time. Some of these countries are evaluating VigiFlow as their database system, which would facilitate ICSR submission to UMC.

European Economic Area (EEA)

The UMC focus to get complete and timely reporting from EEA countries continues. In March we could report a much better reporting from EEA countries than a year earlier. However, during the last six months

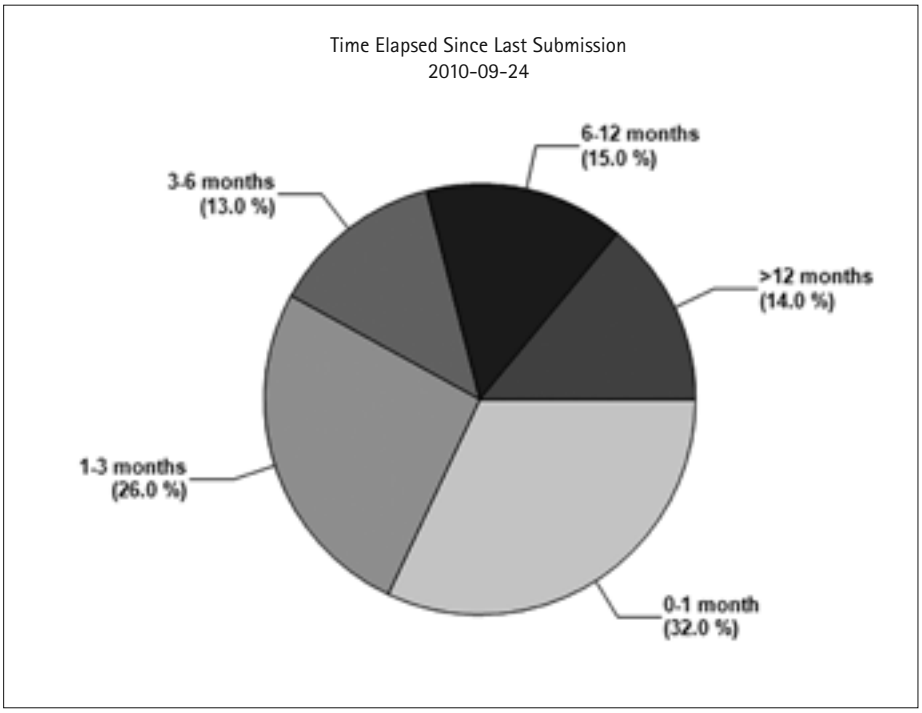
Figure 3. Country distribution in VigiBase



the reporting situation has become slightly less favourable; two-thirds of all EEA countries (18 countries) have reported during the last three months, whereas six months ago 23 countries had reported within the requested time frame.

Since we know that one of the main reasons for not complying with the requested frequency of ICSR submission is technical, in particular the complication for European countries to report both to the European Medicines Agency and to the UMC, UMC staff have contacted some countries and offered site visits to try to help overcome these difficulties. We hope that from these visits we will be able to report an improvement in the next half-yearly ICSR submission statistics report. Some highlights from the site visits are given on page 18-19.

Figure 4. The time since countries last submitted reports to VigiBase



VigiSearch use

The UMC is undertaking an initiative within the WHO Programme for International Drug Monitoring to encourage member countries which do not access the global ICSR search tool VigiSearch™. VigiSearch is available free of charge for members of the Programme over the internet, but other authorized enquirers are charged for their search.

What is VigiSearch?

VigiSearch is a powerful search tool which can be used to find individual case safety reports (ICSRs) collected in VigiBase from all participating countries. Searches are facilitated by several filter options and the result is presented as a statistical overview and a line listing of the individual cases; printouts are possible too.

Data mining with VigiMine

In the integrated VigiMine™ module users can generate a quick statistical overview of reporting for a combination of drug – adverse reaction and get information on the disproportionality measure for that combination, i.e. has it been reported more often, less often, or as often as expected compared to the background of the entire database. The filters can single out combinations which present a disproportionate reporting rate.

Accra seminar

UMC staff will be talking to national centres staff at the meeting in Accra at the end of October to encourage more use of the tool and answer questions about its functions. In addition all national centres not currently using VigiSearch will be contacted directly.

Pharmacovigilance Systems: a comprehensive approach

Jude Nwokike, Senior Technical Manager, Management Sciences for Health, MSH

Background

Access to medicines in developing countries is improving due to the significant contributions of global initiatives, such as the US President's Emergency Plan for AIDS Relief; the President's Malaria Initiative; the Global Fund to Fight AIDS, Malaria and Tuberculosis (Global Fund); the Global Drug Facility; and others. These initiatives have made unprecedented funding available to the developing world to increase access to antiretroviral therapies (ARV), anti-malarials, and anti-TB medicines. However, increased access to essential medicines is currently not coupled with significant attention to the safety and effectiveness of these medicines. Few developing countries have the structures, systems, or resources in place to support medicine safety activities, and often lack unbiased, evidence-based information to help guide treatment decisions and promote appropriate use of medicines.

To address these gaps, the USAID-funded Strengthening Pharmaceutical Systems Program (SPS) hosted a *National Pharmacovigilance Systems: Ensuring the Safe Use of Medicines* conference from 16th to 18th August 2010, in Nairobi, Kenya. This conference aimed to provide participants with a framework for a systems-oriented approach towards building, strengthening, and optimizing medicines safety/pharmacovigilance systems at the country level. It focused on how countries can assess their pharmacovigilance systems and develop phased interventions as part of a comprehensive national medicine safety system.

30 countries represented

More than 100 participants representing ministries of health, medicines regulatory authorities, non-governmental organizations (NGOs), universities, donors, and other partners from more than 30 different countries participated in the conference, which was conducted in English with simultaneous French translation. (The list of attendees is available from http://www.msh.org/projects/sps/SPS-Documents/upload/sps_pv_conference_participants_aug2010.pdf.)

Summary of proceedings

The conference began with global pharmacovigilance initiatives including the efforts of the WHO Programme for International Drug Monitoring. The conference then focused on systems-based approaches to comprehensive safety surveillance. The systems approach provides a conceptual framework and operational approach to strengthen pharmacovigilance systems and stresses the intersection of people, functions, and structures to arrive at local decisions that prevent medicine-related problems and reduce morbidity and mortality. This approach highlighted the need for building capacity to undertake both passive and active surveillance activities and the complementarity of the two approaches in ensuring a robust system for addressing medicine safety issues.* The conference also discussed examples of country and public health programme pharmacovigilance activities and methods and their applications. Many of the participating countries and programmes have invested resources in the development of pragmatic approaches for risk identification in order to monitor safety and effectiveness of HIV/AIDS and malaria medicines. The conference highlighted that there are many active surveillance and related risk assessment activities taking place in developing countries. These studies were largely informed by local needs and safety concerns. Clearly, countries understand the need to evaluate safety signals, particularly when they are of public health importance. The conference also discussed the need for pharmacovigilance system performance metrics. The development and application of the Indicator-based pharmacovigilance assessment tool (IPAT) (http://pdf.usaid.gov/pdf_docs/PNADS167.pdf) was presented. Participants then generated information about country-level barriers, opportunities, stakeholder roles, and sustainability issues. Donor perspectives laid particular emphasis on how countries can include pharmacovigilance activities in their Global Fund applications and how USAID supports pharmacovigilance activities.

The Nairobi conference at work

Key conference conclusions

The conference concluded with the need to adopt a systems approach to creating comprehensive pharmacovigilance systems in developing countries and reinforced the complementary aspects of passive and active surveillance approaches. Although both spontaneous reporting and active surveillance activities are underway in some developing countries, the lack of awareness and coordination of pharmacovigilance activities at the national level results in not recognizing that foundation for a comprehensive medicines safety system may already be in place. The conference also highlighted the need to articulate the results and cost effectiveness of pharmacovigilance activities, the increasingly recognized need for performance metrics, and measuring pharmacovigilance contributions to the prevention of medicines-related problems, reduction of morbidity and mortality, and improvement in treatment outcomes.

Participants in Nairobi, prepared to dip their toes in the waters of pharmacovigilance

*The systems approach is further described in the SPS white paper on Supporting Pharmacovigilance in Developing Countries: The Systems Perspective (avalailable from - http://www.msh.org/projects/sps/SPS-Documents/upload/SPS_PV_Paper.pdf. Conference materials are available at the SPS website - http://www.msh.org/projects/sps/Resources/Conferences.cfm.

Pharmacovigilance consultants in Africa

Sten Olsson

WHO headquarters has adopted a long-term strategy for building advanced pharmacovigilance competence for an African context. The idea is to create a pool of African pharmacovigilance consultants with competence to support the development of sustainable pharmacovigilance systems throughout Africa. A fourth training workshop for consultants was organized in Lomé, Togo 6–10 September, 2010. Consultants participating in the training came from Botswana, Burkina Faso, Cameroon, Ghana, Kenya, Morocco, Nigeria, Senegal, Sierra Leone, Tanzania, Togo and Zimbabwe. Resource persons for some of the sessions were brought from WHO Headquarters, the UMC and UMC-Africa/WHO Collaborating Centre-Ghana. In addition to presentations on the pharmacovigilance situation in the countries represented, the programme covered several methodological and strategic issues including:

- Risk management plans and their applicability in an African context
- Implications of the WHO - Global Fund partnership in pharmacovigilance
- Minimum requirements for pharmacovigilance systems
- The pharmacovigilance tool kit
- Update on African experience with Cohort Event Monitoring and other active surveillance methods
- Using UMC pharmacovigilance tools e.g. VigiFlow, CemFlow and VigiSearch
- Experience of fundraising for pharmacovigilance
- Bridging the gap between AEFI monitoring and pharmacovigilance
- Pharmacovigilance for detecting substandard medicines
- Writing scientific papers in pharmacovigilance
- Expanding the scope of pharmacovigilance
- How to collect information on medication errors.

The course was well supported by the Togolese Ministry of Health and WHO office. The Minister of Health himself received a delegation from the meeting to discuss the situation of pharmacovigilance in Togo (see picture). He kindly offered to provide the National Centre with adequate access to the internet. Local media, both paper-based and digital, covered the event and gave local attention to issues of medicine safety. The local host, primarily and eminently represented by Edinam Agbenu, made sure that participants felt very welcome in Togo. An important conclusion of the workshop was that pharmacovigilance has gained a considerable momentum on the African continent and a critical mass of competence in a wide range of areas is available. The network of consultants could now be coordinated from the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance/UMC-A in Accra, Ghana, with WHO-headquarters and UMC operating as back-up and support organizations.

Alex Dodoo, Shanthi Pal, Mr Komlan Mally (Togo Minister of Health), Edinam Agbenu, Ralph Edwards, Sten Olsson at the meeting in Lomé

CEM In Nigeria

Osakwe A I, Suku C K,
National Pharmacovigilance Centre, Nigeria

The National Pharmacovigilance Centre (NAFDAC) in collaboration with its partners has commenced activities for scale-up of the pilot Cohort Event Monitoring (CEM) programme of Artemisinin-based Combination Therapy (ACTs), conducted in 2009 from a cohort of 3,000 patients to 10,000 patients.

CEM is an active pharmacovigilance method and the broad objective of this particular programme is to evaluate safety in the use of ACTs among populations in Nigeria. We aim to develop the safety profile of ACTs used in Nigeria specifically Artemeter-Lumefantrine (AL) and Artesunate+Amodiaquine (AA) combinations, through active follow-up of patients treated with the monitored medicines and by recording any adverse event they may experience.

Activities for the scale-up started with a two-day review meeting at which all the tools and processes employed for the pilot phase of the programme were reviewed with a view to improving the outcome of the scale-up. The review meeting was then followed by a three-day training for personnel of the sites that will be engaged for patient enrolment in the scale-up. A pre-workshop evaluation of participants' knowledge of pharmacovigilance showed an average score of about 63% with the highest and lowest scores being 95% and 15% respectively. Although participants' knowledge was not assessed immediately after the workshop, the Centre plans to use the upcoming on-site training for CEM site personnel to evaluate participants' short-term retention of knowledge imparted during the training. The on-site training is planned to take place not later than two months after the initial training and just before commencement of patient enrolment.

The training was facilitated by in-country experts on pharmacovigilance and malaria. Participants included healthcare providers (doctors, pharmacists and nurses) working in 18 healthcare facilities including community pharmacies spread across the six geopolitical zones of Nigeria. The full details of the training including contact details of participants and all presentations made at the training can be found on the NAFDAC website using the link www.nafdac.gov.ng (click on NEWS & EVENTS then click on COHORT EVENT MONITORING to view the full report and download all presentations).

Regulatory websites

Geoffrey Bowring

Staff at WHO last year completed an eight-year re-assessment of the websites of medicines regulatory agencies; the results have recently been published.

The number of relevant agency sites monitored had risen to 116 in 2009 (from 51 in 2001). In 2009 87% of agencies in the WHO EURO region had their own website compared to 35% in the WHO AFRO region. In terms of levels of income (according to World Bank criteria) low income countries are, not surprisingly, less likely to have a medicines site than a country from the high income category.

Given the importance of the internet for both health professionals and patients in obtaining information about medicines, the authors note that between 2001 and 2009 there were improvements in most of the criteria used by the researchers to assess agencies' websites.

There was a particular improvement in the presentation of pharmacovigilance matters. From 80% of sites scoring inadequately and only 12% 'good' in 2001, eight years on only 18% were deemed 'inadequate', while 43% were 'good', offering information on how to report ADRs and publishing safety alerts. The authors note however that most sites are not providing adequate information on basic statistics such as medicines consumption, regulatory authority activities, or a country profile. They commend the user-friendliness of the United Kingdom and Denmark sites and praise the comprehensive data available from the US FDA.

Medicines Regulatory Authority websites: Review of progress made since 2001
Cornips C, Rägo L, Azatyan S, Laing R. *International Journal of Risk & Safety in Medicine;* 22 (2010), 77-88.

Organization of medicines regulatory authority web sites
WHO Drug Information; Vol 24, No 2, 2010, 91-98.

DSRU postgraduate courses

Lisa Harvey, Manager of Education and Training, DSRU

The Drug Safety Research Unit (DSRU) in Southampton, UK, is a well-established provider of high-quality training in the field of drug safety, with over a decade of experience. The first students have now registered on the DSRU's new postgraduate courses in Pharmacovigilance. The Postgraduate Certificate (PgC), Diploma (PgD) and Masters (MSc) are accredited by the University of Portsmouth and are aimed at staff from the pharmaceutical industry, regulatory bodies and academia.

Following market research, we determined that there is still an unmet need for quality accredited training in pharmacovigilance. Many delegates already attend several of our two-day training courses covering all aspects of drug safety. We wanted to offer these delegates the opportunity to gain a recognised university qualification. So we set out to construct a flexible postgraduate programme, based on attendance at DSRU courses, besides completion of pre- and post-coursework.

All students must pass three 'core' units, and in addition will receive guidance in a selection of further optional units to ensure

that key competencies are met. These are part-time courses and the PgC, PgD and MSc must be completed within a total of 2, 4 and 7 years respectively. Students may register to start in September, January or June.

Delegates who have attended a relevant DSRU course in the last two years may count that course towards the PgC or PgD by completing the necessary coursework. Delegates who have attended similar accredited training elsewhere may claim for Accredited Prior Learning (APL). Relevant experience in pharmacovigilance may also be considered.

Dr Deborah Layton, Academic Partner Contact at the DSRU, states, "Most of the course materials, including assessments, will be available to students through Victory, the University of Portsmouth's virtual learning environment. This excellent site also provides features to encourage student networking, allowing students to keep in touch virtually with their peers and teachers." Amongst the recommended reading for these courses is the 2010 edition of the UMC's "Expecting the Worst". Professor Saad Shakir, Director, commented, "We are delighted to welcome the first students onto our new postgraduate programmes".

For further information, contact lisa.harvey@dsru.org or visit www.dsru.org.

New EU education programme

Sten Olsson

A new European Union-funded programme in pharmacovigilance and pharmaco-epidemiology is about to come on-stream.

Eu2P is aiming to improve the understanding of medicines-related risk by developing a European training and education 'platform' in pharmacovigilance and pharmaco-epidemiology for those working in academia, industry and regulatory bodies. Seven university departments in France, Netherlands, UK, Italy, Spain and Sweden, the EMA and the French medicines agency, along with fifteen major pharmaceutical companies, form the Eu2P consortium.

The programme will offer courses in pharmacovigilance and pharmaco-epidemiology, with specialisations in benefit assessment, regulatory aspects, risk quantification, public health and risk communication; and award Eu2P certificates, Masters and PhDs recognised by academia, industry and regulatory bodies.

Eu2P is gearing up to offer its first courses in the autumn of 2011. These will be in English using a modular approach integrating face-to-face lectures and web-based learning (including video-conferences) through an interactive e-learning platform. Emphasis will be put on hands-on training to maximise post-training employment opportunities.

The Eu2P project website address is www.eu2p.org.

2011 UMC course

Anna Hegerius

The popular and much appreciated two-week pharmacovigilance course in Uppsala is scheduled for 2-13 May. With a continuous high demand for training, we expect the places on the course to be filled with an interesting mix of participants from around the globe. People representing regulatory authorities, pharmaceutical companies and other institutions should apply.

The course consists of different modules concentrating on spontaneous adverse reaction reporting, pharmacoepidemiology and good communications. In the previous course, parallel sessions with a focus on industry were introduced. This was a success and we hope that the number of representatives from industry settings will increase. The full agenda is still to be finalised but more detailed information and the application form can be found on the UMC website under 'Promotion and Training'.

FP-7 update

Ennita Nilsson

First year of PROTECT completed

The UMC is one of the co-leaders of work package 3 within PROTECT (Pharmaco-epidemiological Research on Outcomes of Therapeutics by a European Consortium), aiming to look at methods for signal detection with an overall objective to develop new methods, and assess existing ones, for signal detection (SD) from spontaneous reports, electronic health records and clinical trials. PROTECT is a collaborative European project that comprises a programme to address limitations of current methods in the field of pharmacoepidemiology and pharmaco-vigilance. The overall goal of PROTECT is to strengthen the monitoring of benefit-risk of medicines in Europe.

The PROTECT Project has just completed its first year and significant results are starting to emerge. The construction of a structured database for European centrally authorized products within this work package is now well under way with substances extracted and mapped to standard MedDRA terms. The use of free text extraction methods to save manual resources has been explored and is looking promising. To date the project has already piloted data set of 350 entries of European Summary of Product Characteristics (SPC) have now been encoded in structured format. Within this sub-package UMC has assisted with free text extraction algorithms that will substantially reduce the amount of manual work to extract MedDRA codes from SPCs in the future.

Study protocols have been agreed for the bench-mark study of different measures of disproportionality analysis in different data sets within this work package and an evaluation of signal detection at different levels of the MedDRA hierarchy. The execution of these two studies is scheduled for project year 2. A draft survey for the characteristics of major ICSRs data sets has been piloted and agreed. The full survey is to be completed during project year 2.

Monitoring Medicines first year

The Monitoring Medicines project has just completed its initial year and is now continuing with its planned objective to enhance patient safety in the next 2½ years. The Monitoring Medicines project has 13 sub-packages, and we are pleased to record that Ola Caster, Anna Kindlundh-Högberg, Johan Hopstadius and Niklas Norén from the UMC have completed Work Package 7, which aimed to derive novel indicators of drug dependence on individual case safety reports. Their work consisted of three major parts: a literature study to identify drugs known to be dependence-liable; development of new indicators; and evaluation of the new indicators along with already available ones, e.g. single ADR terms and relevant standardised MedDRA queries. The derived indicators performed well in the evaluation, allowing for earlier detection of some dependence issues relative to the other indicators, while at the same time offering a low rate of false discoveries.

The Monitoring Medicines project is coordinated by Uppsala Monitoring Centre working in a consortium with 11 partners in Europe, Asia and Africa, (including WHO). The project, which started in September 2009, will run for a further 2½ years. The full project title is, 'Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes', and is funded by the Seventh Framework Programme (FP-7) of the Research Directorate of the European Commission (EC).

Introducing RACS

Richard Hill

Earlier this year, a new department 'Pharmacovigilance Services' came into being at the UMC. Here the work of RACS is described.

RACS functions

The name *Reporting, Analysis & Country Support* was chosen to reflect the main functions performed in our Section. In essence, RACS deals with all aspects of the spontaneous reporting programme, from helping National Centres to participate in the programme, all the way through to producing signals based on the reports in VigiBase. For management purposes, RACS has two main teams: Country Support and Analysis. However, most RACS staff perform work belonging to both teams.

Country Support

RACS is the main point of contact with UMC for countries participating in the WHO Programme for International Drug Monitoring. We provide assistance to countries in being part of the Programme, including help with the use of UMC tools (particularly VigiSearch and VigiFlow), and also seek feedback from countries in order to improve the tools and services offered by the UMC.

We are currently in the process of establishing better methods for countries to provide feedback regarding their use of UMC tools and services, and suggestions for future changes. This will include setting up user-groups specific to VigiFlow, VigiSearch, and Signals, amongst others.

The annual National Centres meeting is an important occasion for us to speak with National Centre staff, but may not provide sufficient time to understand the specific issues and requirements for individual centres. In order to help us understand how National Centres work and how we can help them, this year RACS staff have visited a number of National Centres across Europe, including those in Serbia, Lithuania, Poland, the Czech Republic, and Romania. We do hope to continue and expand these visits in the future.

Reporting

RACS staff receive reports from National Centres and start the process of upload into VigiBase. We work to ensure that reported adverse reactions are correctly mapped to corresponding WHO-ART and MedDRA terms. We also provide support to member countries regarding the implementation of the E2B reporting standard. A key goal for 2011 is to improve the quality of reports in VigiBase; that is, to reduce the amount of missing information in reports, by providing regular feedback to National Centres regarding their reports.

Analysis

On behalf of National Centres and together with our volunteer external signal review panel, we perform regular signal detection on reports in VigiBase, and make results available to National Centres, primarily through the restricted SIGNAL document. We are continuously working to improve the signal process, both in terms of the number and type of signals detected, but also the relevance of the signals to National Centres. RACS staff also have the responsibility of performing customised searches on VigiBase data for both WHO Programme members and external (paying) customers.

Some of the RACS team: Helena Wilmar, Jerry Labadie, Hanna Pedersen , Cecilia

Training

RACS staff are involved in much of the training that is done by UMC, both internally and at external training courses either run by UMC (such as the biennial Uppsala pharmacovigilance course), or where UMC is invited to participate. For example, we are commonly asked to provide training in signal detection, in the use of VigiFlow and VigiSearch, and in the implementation of E2B.

Other

In addition to the key functions described above, RACS has a number of staff who work in the more specific areas of herbal/traditional medicines, vaccines, and medical terminologies (including the maintenance and updating of WHO-ART).

RACS staff

Richard Hill	Manager, RACS
Helena Wilmar	Team Leader, Country Support
Elki Sollenbring	Country Support, Training
Sara-Lisa Fors	Country Support
Hanna Pedersen	Country Support
Jeanette Johansson	Team Leader, Analysis
Solmaz Gareh Chaie	Analysis
Sara Hult	Search Services, Analysis
Cecilia Biriell	Senior Specialist
Mohamed Farah	Senior Specialist, Traditional Medicines
Jerry Labadie	Vaccine Specialist; other clinical advice as required

Biriell, Richard Hill, Sara Hult, Elki Sollenbring, Solmaz Ghareh Chaie, Sara-Lisa Fors

RACS relationship with other areas of UMC

Pharmacovigilance is of course the basis for UMC's work, and therefore RACS staff work closely with the other sections in the Pharmacovigilance Department, and staff from other departments. RACS provides user input regarding desired improvements, and participates actively in the development process with the Pharmacovigilance Product Management Section, responsible for the development of the tools and services (such as VigiFlow and VigiSearch) created by UMC. RACS will work closely with the Education and Training Section when it is up and running.

Research & Development

RACS works with the UMC Research Department to develop the signalling and analysis process, as well as on more complex analysis projects which may result in publications in medical journals, or conference presentations (for example: Tengstrand M, et al. Alopecia in Association with Lamotrigine Use: An Analysis of Individual Case Safety Reports in a Global Database. *Drug Safety* 2010; 33(8): 653-658).

Production, Development, Quality (PDQ)

PDQ develops and maintains the systems essential for RACS to do our work. Key processes include the validation of uploaded ICSRs, and regular monthly updates of VigiBase data accessible through VigiSearch. PDQ also has created a range of tools and statistics which are used to monitor the functioning of the reporting program. These tools will be an integral part of our plans to increase feedback to National Centres regarding their reporting (see report in UR49, p12-13).

Drug Dictionary (DD)

Where required, RACS assists the DD group in mapping drug names from reports onto entries in the WHO family of drug dictionaries. As mentioned above, RACS maintains special expertise in herbal/traditional medicines and vaccines.

Global Outreach Secretariat (GOS) and UMC-Africa (UMC-A)

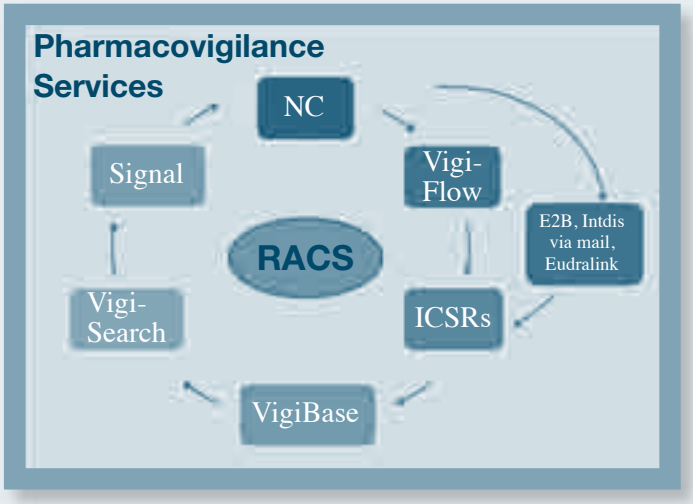
GOS is currently the main contact point for potential new member countries of the WHO Programme. GOS and RACS work together in communicating with new partners. RACS works with UMC-Africa as required regarding participation of African countries in the WHO Programme, and earlier this year participated in a two-day online training to staff from UMC-A, Kenya, and Sierra Leone.

Contacting RACS

RACS staff can be contacted via the shared 'VigiBase' mailbox: vigibase@who-umc.org.

Information about the work of RACS appears regularly in *Uppsala Reports.* We also distribute the SIGNAL document free-of-charge to all National Centres. If you do not currently receive SIGNAL but would like to do so, please contact us.

Three of the RACS staff (Richard Hill, Helena Wilmar, and Sara-Lisa Fors) will attend this year's National Centres meeting in Accra, Ghana; we look forward to seeing you there!



RACS deals with the receipt of ICSRs from National Centres. Many National Centres use VigiFlow to handle their reports, for which Country Support have first-line responsibility and check the collection of ICSRs from VigiFlow into VigiBase. ICSRs also come in other formats (E2B and Intdis) and via other routes (e-mail or Eudralink, for instance). This is where the Reporting part of RACS has their focus, while Technical Solutions work for example with ICSR future formats, the DD team work on coding of uncoded drugs on reports, and the Research Department work with different methods to extract data and statistics from VigiBase.
Outputs from VigiBase are presented in VigiSearch – the search tool available to all member countries and review panel members. The Analysis team in RACS use VigiSearch to find cases when analysing signals. Output of analysis of case reports retrieved from VigiSearch may result in signals of drug related problems. The Analysis team of RACS, the Research Department and the Signal Review Panel provide articles for the SIGNAL document which is distributed to all National Centres - to close this circle of ICSRs.

New vaccine reports from FDA

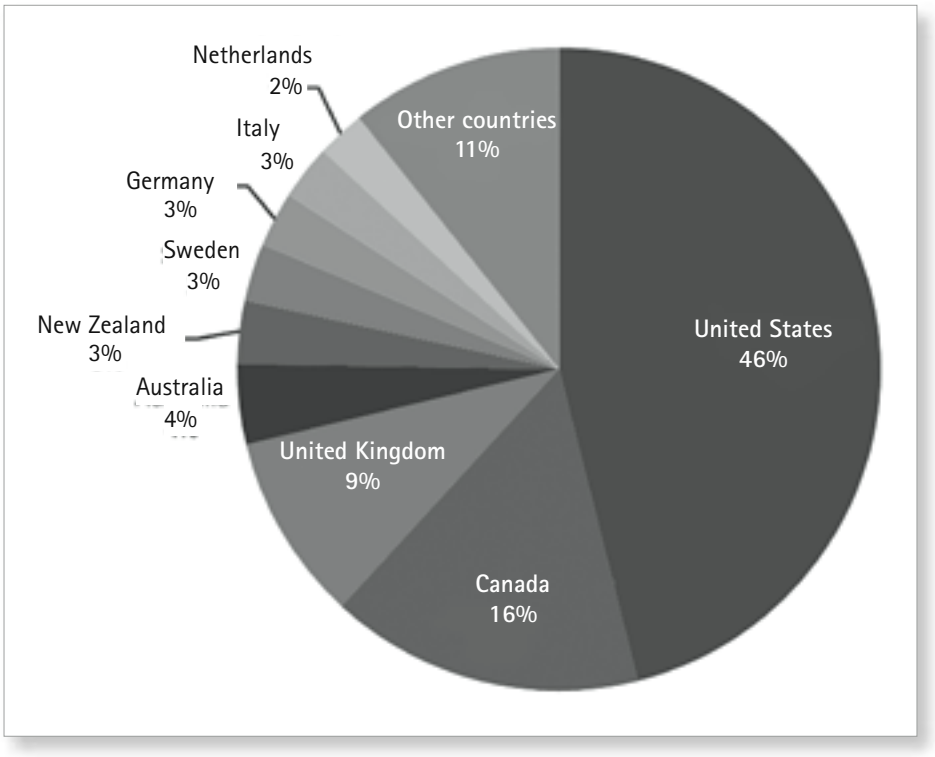
Richard Hill

During this year, UMC has been in discussion with the American FDA about incorporating US vaccine reports in VigiBase™ (the WHO global individual case safety report (ICSR) database). Although the US is the largest single contributor of ICSRs to VigiBase, we had not received vaccine reports from the VAERS (Vaccine Adverse Event Reporting System) programme since 2001.

Significant addition to VigiBase

UMC worked with the FDA and SRA – the contractor that operates the VAERS program for CDC (Centers for Disease Control and Prevention) and FDA – over a number of months to validate the format of the reports. After this was completed, we were sent a CD containing vaccine reports covering the period 1990 to July 2010. At the time of writing, 245,454 reports (reports up to 2007) have been uploaded into VigiBase, and are available for searching via VigiSearch. This figure includes around 140,000 reports that are completely new in VigiBase, and older ones that have been updated from Intdis to the E2B format.

Contribution to vaccine reports in VigiBase, the WHO global individual case safety report (ICSR) database



Country contributions

This batch of reports brings the total number of vaccine reports in VigiBase to 500,538 (8.9% of all reports in VigiBase). Countries contributing the most vaccine reports to VigiBase are shown in the table below:

United States	230,509	46%
Canada	78,915	16%
United Kingdom	47,109	9%
Australia	20,298	4%
New Zealand	15,735	3%
Sweden	14,541	3%
Germany	13,839	3%
Italy	13,822	3%
Netherlands	12,144	2%
Other countries	53,626	11%
TOTAL	500,538	

We now look forward to regular receipt of vaccine reports from the US, and over the coming months, UMC and FDA plan to develop routines for working together on the analysis of these reports.

Visit to WHO Centre in Oslo

Malin Jakobsson

The UMC has one representative in the WHO Working Group for Drug Statistics Methodology under the aegis of the WHO Collaboration Centre for Drug Statistics Methodology in Oslo. Within this group the UMC has an observer role, attending all meetings (two per year: one face-to-face and a video/telephone conference), and actively taking part in the discussions at the meetings. The current UMC representative is myself.

UMC representatives Marie Lindquist, Daniel von Sydow and Malin Jakobsson visited the Oslo centre in September 2010; all the Oslo centre staff attended the meeting. The main discussions were around how the UMC uses the ATC system, as well as the Herbal ATC system produced by the UMC. It was also decided that the two WHO centres will meet every second year.

Vaccine safety news

Jerry Labadie

The UMC's pandemic influenza vaccine adverse event following immunisation (AEFI) monitoring tool PaniFlow™ has been developed in close collaboration with Swissmedic, the national regulatory authority in Switzerland. Swissmedic has recently published the first evaluation of PaniFlow. Some of the salient observations are:

The majority (>90%) of physicians and pharmacists chose to submit their case reports directly online into PaniFlow.

PaniFlow was a useful and efficient web-based reporting tool that permitted timely monitoring of AEFI associated with pandemic influenza (H1N1) 2009 vaccines, and was acceptable to most healthcare professionals.

The final report of Swissmedic's Vigilance Unit on the pharmacovigilance of pandemic influenza (H1N1) 2009 vaccines can be accessed at: http://www.swissmedic.ch/marktueberwachung/01315/index.html?lang=en

PaniFlow user accounts have been opened for ten countries: Croatia, Georgia, Morocco, Namibia, Nigeria, Serbia, Singapore, Suriname, Switzerland and Turkey. Of these, reports from Morocco, Singapore and Switzerland are already included in UMC's updates on AEFI on A/H1N1 pandemic influenza vaccines.

A/H1N1 Flu Vaccine Monitoring continues

The Director-General of WHO, Dr Margaret Chan, declared the end of the influenza (H1N1) pandemic on Tuesday 10 August 2010. However, the Uppsala Monitoring Centre continues to monitor the AEFI that are reported on A/H1N1 pandemic influenza vaccines, as reports following WHO's deployment of these vaccines in low- and middle-income countries keep coming in to the database at the UMC. Regular updates on AEFI data extracted from Vigibase™ are published on UMC's A/H1N1 Flu Vaccine Monitoring webpage at: http://www.who-umc.org/DynPage.aspx?id=85898 (or www.who-umc.org > What's New > Pandemic Flu Vaccine Monitoring).

Global Network news

Jerry Labadie, UMC's vaccine safety expert, and Adwoa Bentsi-Enchill (WHO-IVB) visited India for a 'Baseline Country Assessment' and to take part in a basic VigiFlow™ training course within the context of the WHO Global Network for Post-marking Surveillance of Prequalified Vaccines (the Network). The Government of India designated Maharashtra State as the participating member of the Network. Currently the Network comprises 11 other countries across the six WHO Regions: Albania, Brazil, China, Iran, Kazakhstan, Mexico, Senegal, Sri Lanka, Tunisia, Uganda, and Vietnam. When countries join the Network the Baseline Country Assessment aims to collect data on selected immunization and related health parameters through interview and review of documentation. These data are used for needs assessment of specific resources and technical support, and for AEFI analyses at a later stage (background rates and denominator data).

Participants of VigiFlow training for member countries of the Global Network for Post-marking Surveillance of Prequalified Vaccines, Mumbai on 3rd and 4th August 2010

A successful, hands-on basic VigiFlow training in Mumbai, Maharashtra was moderated by Miss Shraddha Anwikar and Miss Mitali Bandekar. AEFI were entered in VigiFlow with an emphasis on specific AEFI fields that have been introduced into VigiFlow and will be piloted by the countries in the Network.

The Global Advisory Committee on Vaccine Safety

The Committee held its 22nd meeting in Geneva, Switzerland on 16–17 June 2010. The Committee reviewed:

(i) the safety of pandemic A (H1N1) influenza vaccines

(ii) an apparent increase in febrile reactions following administration of a seasonal influenza vaccine in Australia

(iii) the finding of DNA from porcine circoviruses in rotavirus vaccines

(iv) the safety of live attenuated hepatitis A vaccines

(v) the safety profile of a recently prequalified meningococcal A conjugate vaccine; and

(vi) new data on yellow fever vaccine-related risks.

The Committee also discussed reports of narcolepsy in Sweden and Finland allegedly related to vaccinations with Pandemrix® on 27 August 2010 (see http://www.who.int/immunization_standards/vaccine_quality/pandemrix_narcolepsy/en/index.html).

The full report of the meeting of the Global Advisory Committee on Vaccine Safety, 16-17 June 2010 is downloadable from http://www.who.int/vaccine_safety/wer2010_wer8530.pdf (288kb).

ICH-E2B as the preferred ICSR reporting format

Helena Wilmar and Jessica Nilsson

Within the WHO Programme for International Drug Monitoring the majority (65 out of 100) of the member countries are now using the recommended international electronic ICH-E2B format when sending Individual Case Safety Reports (ICSRs) to the UMC.

What is E2B?

ICH-E2B is a standardized format for transferring data between databases of different structure, defining the type of information as well as the format of the information (using XML document - Extensible Markup Language) to be transferred. The standard is described by a DTD (Document Type Definition) – a scheme of what to transfer and how.

Figure 1. Reporting formats used within the WHO Programme. Intdis is an electronic version of the paper WHO format. E2B includes both ICH-E2B and ICSRs extracted from the VigiFlow system. 'Not specified' includes countries in the process of changing their format to ICH-E2B.

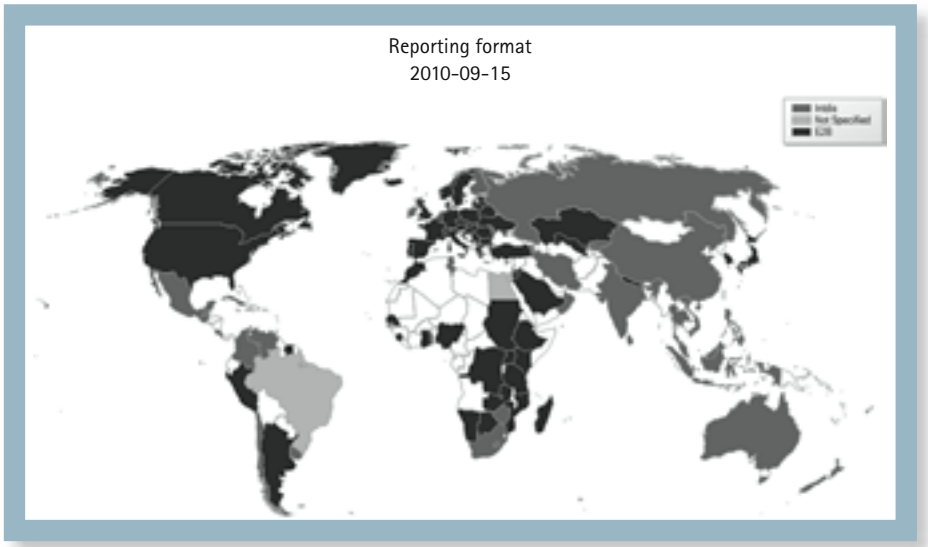


Figure 2. A small extract from a XML file containing one ICSR

```
- <reaction>
    <primarysourcereaction>trillen/beven/fladderen bij baby</primarysourcereaction>
    <reactionmeddraversionllt>9.1</reactionmeddraversionllt>
    <reactionmeddrallt>10045198</reactionmeddrallt>
    <reactionmeddraversionpt>9.1</reactionmeddraversionpt>
    <reactionmeddrapt>Muscle twitching</reactionmeddrapt>
    <termhighlighted/>
    <reactionstartdateformat>102</reactionstartdateformat>
    <reactionstartdate>20061215</reactionstartdate>
    <reactionenddateformat>102</reactionenddateformat>
    <reactionenddate/>
    <reactionduration/>
    <reactiondurationunit/>
    <reactionfirsttime/>
    <reactionfirsttimeunit/>
    <reactionlasttime/>
    <reactionlasttimeunit/>
    <reactionoutcome>1</reactionoutcome>
  </reaction>
- <drug>
    <drugcharacterization>1</drugcharacterization>
    <medicinalproduct>SEROXAT TABLET FILMOMHULD 20MG</medicinalproduct>
    <obtaindrugcountry/>
    <drugbatchnumb/>
    <drugauthorizationnumb/>
    <drugauthorizationcountry/>
    <drugauthorizationholder/>
    <drugstructuredosagenumb>20</drugstructuredosagenumb>
    <drugstructuredosageunit>003</drugstructuredosageunit>
    <drugseparatedosagenumb>1</drugseparatedosagenumb>
    <drugintervaldosageunitnumb>1</drugintervaldosageunitnumb>
    <drugintervaldosagedefinition>804</drugintervaldosagedefinition>
```

Who should use this format?

When using ICH-E2B, countries should have:

1. an ICH-E2B compatible ICSR database in-house, and / or
2. the ability to create and send cases via the web-based ICSR management system VigiFlow

Within the European Union it is mandatory to report ICSRs in ICH-E2B and this is possible by

3. using the EudraVigilance system, hosted by the European Medicines Agency (EMA), as well as the above two options.

How does it look?

Since E2B is an electronic-only format there is no paper form to fill in. Therefore creation of an XML file of the case report is required in order to print it. However, an E2B report may contain more than 200 fields (tags) with information, and therefore is not possible to print on one single page (as is the case with the CIOMS I or WHO format).

What should/can be reported?

The minimum requirements for ADR data to be entered into an E2B case report are the same as for the WHO format.

Mandatory information for an E2B case:

1. Unique identification number of the report (safetyreportid)
2. Country
3. At least one Adverse Drug Reaction (ADR)
4. At least one suspected medicinal drug (preferably the brand name).

As well as the above there are some additional mandatory fields to complete, in order to fulfill the technical requirements of the electronic format.

Compared with the WHO format, there are more options for the ADR information to be recorded in an E2B case report.

Figure 3. A comparison of WHO and E2B formats

	WHO format	E2B format
Age	Date of birth	Date of birth, Age at onset date of the reaction, Age group
Death information	Cause of death (ICD-code), Death date, ADR, Outcome of the case	Cause of death (ICD or MedDRA code), Death date, ICH seriousness criteria, Outcome of the ADR
Outcome	Case level	ADR level
Causality assessment	Case level	ADR/drug level
Free text fields	Only one free text field	Several fields (some up to 20,000 characters long) Patient medical history, Case narrative, Results of tests and procedures, Labeling info, Reporter's comment, Sender's diagnosis, Sender's comment
Parent/child /fetus reports	-	Case report in which the administration of medicines to a parent results in a suspected reaction/event in a child/fetus. Additional data for the parent can be entered in specific parent fields. For example, parent information about Age, Drug names, Route of administration, ADRs, Medical history etc.
Results of tests and procedures	-	Used to capture the tests and procedures performed to diagnose or confirm the reaction/event. Both positive and negative results should be reported.
Literature cases	-	Used for literature article(s) describing individual case report(s), but not for articles used for data analysis.
Linked reports	-	Used to identify reports or cases that warrant being evaluated together. This includes a mother-child pair where both had reactions/events, siblings with common exposure, several similar reports from same reporter (cluster).
Report nullification	-	Used to indicate that a previously transmitted report is considered completely void (nullified). For example when the whole case was found to be erroneous.

Example of an 'illogical' case report

Despite the flexibility of the E2B format where lots of useful information may be coded in different ways on a case report, this could likewise create an illogical summary of the reported ADR data when presented for example in VigiBase. The format in itself does not have any logical checks and ADR data is presented as it was coded in the electronic E2B form; see example below.

Figure 4 is an extract of a case report (PDF output from VigiSearch) where information in the Parent/child report-field indicates Y=Yes. The patient is a 90 year old woman, but one interpretation of the presented data is that the woman is the actual child, which is not logical. However, by checking the coded ADR data in the electronic E2B case report, information has been recorded in a parent specific field (probably by mistake) and that is the reason why the Parent/child report-field is indicated with Y=Yes.

The UMC is happy to provide assistance to countries in the correct implementation of E2B.

Figure 4. Extract from a sample 'illogical' case report; output via VigiSearch.

Report information					
Type of report	***Date entered into vigibase***	***Reporter type***	***Country***	***Original format***	***Quarter of entry***
Spontaneous report	20100113	Physician	Germany	E2B	20100331

Serious case	***Serious criteria***	***Death date***	***Fatal case***	***Parent/child report***
Yes	-		-	Y

Patient information						
Sex	***Birth year***	***Age at onset***	***Age group***	***Weight***	***Height***	***Last menstr. date***
Female	1915	90 Year(s)	Elderly	55	161	-

Welcome in Warsaw

Helena Wilmar and Richard Hill

Two staff from the Reporting, Analysis & Country Support team, Richard Hill and Helena Wilmar, had the great pleasure to pay a September visit to the National Centre in Warsaw, the Pharmacovigilance Unit within 'The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products'. The meeting was opened by the President of the Office, Grzegorz Cessak. We gave a background UMC presentation, then the Pharmacovigilance Unit gave an overview of their work, where the main responsibilities are collecting and assessment of Individual Case Safety Reports (ICSRs), and the safety monitoring of medicinal products use. The team that works with pharmacovigilance issues consists of ten staff (four pharmacists, three doctors and three administrative staff).

Monika Trojan, who is a senior specialist and pharmacist, gave a demonstration of the current Polish in-house ICSR database (compatible with ICH-E2B) and how ICSR submissions are handled with different organizations. Discussions and recommendations on how to improve and facilitate the submissions to European Medicines Agency (EMA) and UMC were held, and we also received valuable input for future consideration.

Staff from the Polish Pharmacovigilance Unit and UMC delegation. From left: Helena Wilmar (UMC), Magdalena Tarkowska, Magdalena Marcinkowska, Richard Hill (UMC), Anna Arcab, Magdalena Budny and Monika Trojan.

The last item on the agenda was a short UMC demonstration of the tool VigiSearch. Two of the NC staff use VigiSearch regularly in their pharmacovigilance work, but were less familiar with the use of VigiMine. Thoughts, wishes and recommendations for improvements from the Polish centre were shared with us. Overall this was a very rewarding encounter where UMC's delegation met dedicated staff. Thank you to all staff for a very well-organized and warm-hearted meeting in Warsaw!

Czech visit

Sara-Lisa Fors

The UMC visitors and the Czech national centre team: standing: Kristína Vavrušková, Monica Plöen; sitting: Sara-Lisa Fors, Lucia Kováťová, Zuzana Chomátová and Veronika Deščíková.

In mid September Monica Plöen and Sara-Lisa Fors from the Pharmacovigilance Services department paid a visit to the Czech pharmacovigilance unit at the State Institute for Drug Control in Prague. The visit was a step in the current UMC focus on EMA countries. The purpose was for UMC to learn how the daily work of report handling is performed, how the Czech unit receives information from health practitioners, industry and patients, and to come up with suggestions on how to improve the reporting to the UMC and also to inform about UMC activities and services.

The meeting started with a demonstration of the Czech reporting system from the data manager Kristína Vavrušková. Discussions and suggestions for how to improve and facilitate the submissions to the UMC were held and some issues could be solved on the spot.

The next day Sara-Lisa gave a presentation for the Czech pharmacovigilance unit staff about UMC activities in general, while Monica showed in detail how to use VigiSearch™ and Vigimine™ and how these UMC services could facilitate the daily work of a national centre. Useful discussions were had on how to improve the tools to make them more user-friendly.

We thank the Czech team warmly for hosting us during these two days.

UMC goes east – a report from Bucharest

Cecilia Biriell

The last of the UMC's autumn trips to European national centres took Cecilia Biriell and Magnus Wallberg to the National Agency of Medicines and Medical Devices (NAMMD) in Bucharest, Romania. The visit was very fruitful for both sides and great hospitality was shown to us from the Romanian centre.

The hospitality started at the airport where we were met by a car from the agency and the agency's own translator Mrs Mihiaela Văcăriu. We were taken straight on a tour of the centre of the city. Bucharest has a long and interesting history, evident in great buildings from various periods. Many were destroyed during the wars and in the big earthquake in 1977 and have been replaced by newer ones. The most well-known building is probably the enormous government building built under Ceausescu from 1984-1989.

The following morning we were welcomed to the Medicines Agency by Dr Robert Ancuceanu, Vice-President of the Agency, and the staff of the Pharmacovigilance section. The Pharmacovigilance section consists of three persons; Dr Daniela Stanciu, head of the section, Dr Daniela Pompniu and Dr Irina Vaduva. In addition Dr Nela Vîlceanu, head of the European Procedures Department attended the meeting.

Daniela Stanciu presented the activities of the Pharmacovigilance section and its difficulties in handling reporting to both UMC and EMA. Romania has been member of the EU for only three years and has had to put in great efforts to comply with EMA regulations. The Romanian Pharmaco-vigilance section is using VigiFlow from UMC, but section staff were not clear how VigiFlow can best be used for submitting ICSRs to both UMC and the EMA.

Cecilia presented the activities of UMC and in particular how the Romanian pharmaco-vigilance section can make best use of UMC's services. Terminology issues were discussed and it was agreed that the best option for the Romanian centre, and all others who have to report to EMA using MedDRA, was to use this terminology instead of WHO-ART when reporting to the UMC.

Magnus went through various functions of VigiFlow and explained about how to export and import ICSRs in VigiFlow in a controlled way via the Submission Manager. He demonstrated the best use of VigiFlow when sending and receiving ICSRs to and from EMA and pharmaceutical companies.

After a heavy day of pharmacovigilance discussions we were invited to a traditional Romanian restaurant 'Caru' cu Bere' where we were served typical Romanian food: fresh cheese, sausages and sauerkraut. We were also entertained by traditional Romanian folk dancers.

Staff of the Romanian agency, from left: Dr Daniela Stanciu, Head of pharmacovigilance, Alina Spiridon, Dr Irina Vaduva, Dr Nicolae Fotin, Dr Daniela Pomponiu, Dr Nela Vilceanu

Day two started with a thorough presentation of VigiSearch including how and when to use it. It was pointed out that VigiSearch is freely available for all National Centres within the WHO Programme. The VigiSearch tool was demonstrated 'live' on a substance of special interest for the NAMMD staff. Lots of discussion was given over to the VigiMine tool, which is an integrated module in VigiSearch. The day ended with some problem-solving directly in the Romanian VigiFlow database.

After our visit we are convinced that the Romanian centre can use VigiFlow optimally and can now reach a more rational way of handling their reports.

Kew visit

Elki Sollenbring

Mohamed Farah and I went to London in September to meet Bob Alkin, Information Projects Manager at the Royal Botanic Gardens, Kew. The purpose of our visit was to explore possibilities to improve the collaboration UMC has with Kew Gardens relating to the accepted scientific plant names included in the WHO Herbal Dictionary (WHO-HD).

During the meeting we had the opportunity to talk with Chris Leon, Alan Paton and Debbie Shaw who are involved in different aspects of this project. We were very pleased with the outcome from this meeting which means that all scientific plant names mentioned in the WHO-HD will be reviewed by Kew Gardens.

A working lunch for Elki Sollenbring, Debbie Shaw, Chris Leon, Alan Paton, Mohamed Farah and Bob Alkin

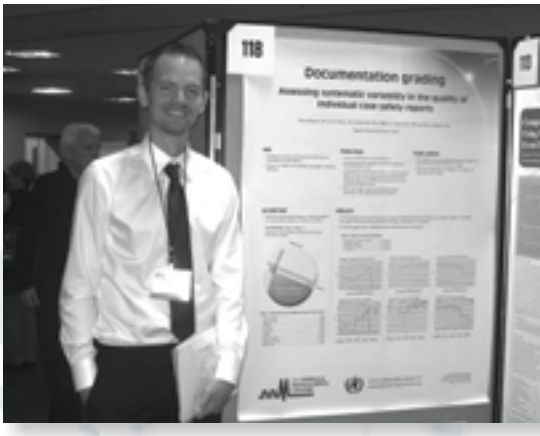
The view from Brighton

Jeanette Johansson

The 26th International Conference on Pharmacoepidemiology and Therapeutic Risk Management was held in the seaside town of Brighton on the south coast of England with around 1,000 attendees; the large number of oral presentations meant that at times there was a total of six parallel sessions. The UMC was represented by a team of delegates, two oral presentations ('Benefit-Risk Assessment Based on Ordered Clinical Outcomes' and 'Early Indicators of Drug Dependence'), a poster on documentation grading and a small exhibition booth.

A highlight of the pre-conference courses was an inspiring morning on 'Intermediate Pharmacoepidemiology: Concepts, Data and Methods' co-ordinated by Dr Alec Walker of Harvard School of Public Health.

There were sessions looking at experiences during the deployment of H1N1 vaccines and two interesting symposia organised by the Medicines in Pregnancy Special Interest Group.



Tomas Bergvall with his UMC poster in Brighton

Participation by regulators as speakers seemed much higher than in previous years, although was somewhat dominated by European and North American regulators.

Professor Stephen Evans was installed as the new Society President.

Recent publications from the UMC

Alopecia in Association with Lamotrigine Use: An Analysis of Individual Case Safety Reports in a Global Database
Tengstrand M, Star K, van Puijenbroek EP, Hill, R.
Drug Safety 2010; 33 (8): 653-658.

This study examined the association between lamotrigine and alopecia by outlining characteristics of the reports in the WHO global ICSR database, VigiBase up to 1 April 2009. Lamotrigine was suspected of being involved in the development of alopecia in 337 patients, from 19 countries. The UMC continues to receive such reports, and this adverse reaction may potentially affect compliance, and thus result in decreased efficacy of the treatment regimen to the detriment of patient outcomes.

Large-scale regression-based pattern discovery: the example of screening the WHO global drug safety database
Caster O, Norén GN, Madigan D and Bate A.
Statistical Analysis and Data Mining (2010), 3: 197–208. doi: 10.1002/sam.10078".

This paper is the first to describe disproportionality screening of an entire ICSR database using regression rather than standard pairwise measures such as the IC or PRR. Specifically, it investigates to what extent so-called shrinkage logistic regression can mitigate two problems inherent to standard measures, confounding by co-reported drugs, and masking, and whether this makes any difference in practice. The results show that the theoretical benefits of regression do manifest themselves in practice. However, because regression is less transparent than standard measures, and because the empirical results showed that it sometimes discovered known drug safety issues later than the IC, the conclusion is that regression be used as a complement rather than a replacement to existing measures.

Pharmacovigilance Activities in 55 Low- and Middle-Income Countries: A Questionnaire-Based Analysis
Olsson S, Pal SN, Stergachis A, Couper M.
Drug Safety, 33 (8), 1 August 2010 , pp. 689-703.

There is a need to measure and understand existing conditions and pharmacovigilance initiatives in low- and middle-income countries, as few investigations have been carried out in recent years. Between March and July 2008 a questionnaire was sent to 114 representatives of countries participating in the WHO Programme for International Drug Monitoring (excluding International Conference on Harmonization countries, and Australia, Canada, New Zealand and Switzerland). The questionnaire aimed to collect information on the structure, resources, functions and achievements of pharmacovigilance systems in low- and middle-income countries, focussing on pharmacovigilance activities supported by national health authorities, including public health programmes. Challenges and barriers to promoting pharmacovigilance in such countries were identified and it was concluded that a pharmacovigilance strategy in these settings needs to help build systems that can serve the purpose of multiple health conditions.

Consideration of the desirable features and possible forms of practical indicators of the performance of pharmacovigilance centres
Kshirsagar NA, Olsson S, Ferner RE
International Journal of Risk & Safety in Medicine; 22 (2010), 59-66.

First, Catch Your Signal!
Edwards, I. Ralph; Lindquist, Marie
Drug Safety 2010; 33 (4): 257-260.

Placebo Harm
Edwards, I. Ralph; Graedon, Joe; Graedon, Terry
Drug Safety 2010; 33 (6): 439-441.

A Decade of Data Mining and Still Counting
Hauben, Manfred; Norén, G. Niklas
Drug Safety 2010; 33 (7): 527-534.

What do stakeholders think about pharmacovigilance?
Edwards, I. Ralph; Graedon, Teresa
Drug Safety 2010; 33 (8): 619-621.

Reflections on Attribution and Decisions in Pharmacovigilance
Caster O and Edwards IR
Drug Safety 2010; 33 (10): 805-809.

Other recent papers of interest

WHO's International Drug Monitoring – The Formative Years, 1968–1975: Preparatory, Pilot and Early Operational Phases
Venulet J, Helling-Borda, M.
Drug Safety 2010, 33 (7): 1 July, pp. e1-e23(23)

This is an important first-hand account of the early years of the WHO Programme and international efforts in drug safety by two pioneers in pharmacovigilance, drawing on core contemporary documents.

Medicines Regulatory Authority websites: Review of progress made since 2001
Cornips C, Rägo L, Azatyan S, Laing R.
International Journal of Risk & Safety in Medicine; 22 (2010), 77-88.

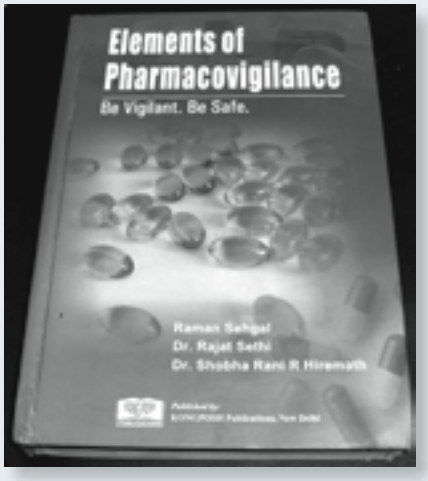
Organization of medicines regulatory authority web sites
WHO Drug Information; Vol 24, No 2, 2010, 91-98.

Overview and comparison of post-marketing drug safety surveillance in selected developing and well-developed countries
Vaidya SS, Guo JJ, Heaton P, Steinbuch M.
Drug Information Journal, Vol 44 (2010): 519-533.

A detailed but now somewhat out-of-date review of drug safety regulation, government organization, ADR reporting and safety monitoring systems.

New book

We have received a new introductory book on pharmacovigilance 'Elements of Pharmacovigilance' by Raman Sehgal, Rajat Sethi and Shobha Rani Hiremath. It covers theoretical and practical aspects of pharmacovigilance and is published by KONGPOSH Publications Pvt. Ltd. (Tel: +91-11-26855839, E-mail: kongposhpub@gmail.com, info@kppub.com).



Staff update from the UMC

We take our regular look at staff working around the Centre who have yet to be introduced.

Martin Strömberg

Martin was born in Uppsala and grew up in a nearby suburb. One of the team of systems developers at the UMC, Martin's focus is on systems used for managing ICSRs, such as VigiFlow and PaniFlow.

"I have a MSc degree in computer and systems sciences from the University of Stockholm. Before joining the UMC in the beginning of March 2008, I worked for the Uppsala County Council. The unique UMC atmosphere was a big surprise to me. I believe it is due to the vast span of different personalities within the organizations, combined with the international influence from all national centres."

Married with two daughters, apart from his family and refurbishing the home, his other interests include genealogy, wood-working and sailing.

Mats Jonsson

Mats comes originally from Härnösand, a small coastal town located in the northern part of Sweden, but has lived in Uppsala for 15 years.

Mats works as a database/system developer, especially with the WHO Drug Dictionary. His role is to fill the gap between working with data (how the data is stored on a central computer) and working with user interfaces (what the user sees on the screen) in some of the development projects. So far he has mostly been involved in the technical aspects of how we produce and quality control the WHO Drug Dictionary files which can be downloaded from the web shop. Another area has been adding support for different languages, and enhanced flexibility for different types of dictionaries. "In short you can say that I work with design and implementation of database systems to support the maintenance and production of WHO Drug Dictionary."

Mats has an MSc degree in the biotechnology field from Uppsala University (with a focus on technology and engineering). "Before I started at the UMC I worked with software development for an academic contract research lab in the field of genetics at the Uppsala University Hospital. My mission was to create software tools to help staff keep track of the thousands of test tubes sent to the lab and to merge and quality control results with sometimes millions of data points in a single project. A lot of the skills I learned have been useful at the UMC as well."

Outside work Mats has participated in a number of 'just-for-fun' triathlon races arranged by some of his former colleagues where contestants swim, bike and run in the same race.

"The UMC is rather unknown among the people in Uppsala, so I was surprised by how big the UMC actually is and how many different activities UMC takes part in."

Mats, Kristina and Martin

Kristina Juhlin

"I was born and raised in Oskarshamn in south east Sweden but moved to Uppsala in 2004 to study, undertaking an MSc programme in Engineering Physics, specializing in scientific computing. I completed my Master's thesis on the possibility of using silicon detectors to improve the performance of PET scanners at the institution for Medical Imaging at the 'Kungliga tekniska högskolan' (Royal Institute of Technology) in February this year."

Kristina currently works as a research engineer with data extraction and computation. "What I like most about my work at the UMC is the possibility to combine programming with computation and statistics."

She describes her hobbies as "very normal", such as reading, running, playing computer/video games and watching TV shows – preferably science fiction.

Welcome back Anna

Anna Celén has returned from maternity leave as Anna Hegerius since she got married and changed her surname. She was previously a member of the former External Affairs Department and will continue to work with education and training.

Prize-winning paper

The Editorial Council Scientific Platform in the Netherlands has awarded Jeroen Derijks of the University of Utrecht the Opwijrda Prize 2009 for the paper 'Association between antidepressant use and glucosedisregulatie: evidence based on reported adverse events', published in the Scientific Platform PW 20 February 2009. The results of this study, the Dutch version of a study on antidepressants and hypo- and hyperglycaemia, using the WHO database, strengthened the findings in individual case reports that the use of antidepressants is associated with disturbances in glucose homeostasis. The study found evidence that particular patterns of receptor affinities are influential whether patients on antidepressants develop either hyper- or (paradoxically) hypoglycaemia. The paper illustrates the potential of the UMC's international database for identifying mechanisms underlying differences in ADR profiles of different members in a therapeutic group. Referring to their findings the authors proposed a novel, more pharmacologic, classification of antidepressants. (PW Wetenschappelijk Platform 2009;3(2):22-27. See also: Derijks HJ, De Koning FH, Meyboom RH, et al. Impaired glucose homeostasis after imipramine intake in a diabetic patient. *J Clin Psychopharmacol* 2005;25(6):621-3.)

Software certification for WHO Drug Dictionary

Ola Strandberg

In my role as Vendor Liaison Officer at the UMC, I work with the companies that develop software for our end customers, to ensure that in turn, they enable the best possible use of the WHO Drug Dictionary and other UMC products by pharma companies, CROs, etc. It is important for all customers using our Drug Dictionary for drug safety or clinical research that the UMC data is used fully and its potential is harnessed in their day-to-day work.

In conjunction with the Drug Information Association 46th Annual Meeting in Washington DC, in June 2010, we launched a new software certification programme that helps software developers integrate the WHO Drug Dictionary Enhanced quickly and easily. The certification offers a set of test cases, with associated acceptance criteria, to indicate whether implementation processes are accurate. It also offers software developers free training and a software development kit, including documentation and example programs. Companies that enroll in the programme can use its templates and examples as blueprints for developing solutions that fulfill user requirements. Test cases and associated 'known input/known output' data verify whether solutions have been developed correctly. The software development kit and free training make it easy for IT integrators to realize desired solutions. To date, 16 software development companies have already signed up for the program, and one vendor product, Central Coding from Phase Forward, has already achieved certification.

Work is now continuing to assist companies in getting through the certification process and evolving the requirements for the certification itself. More information can be found at http://www.umc-products.com/certification.

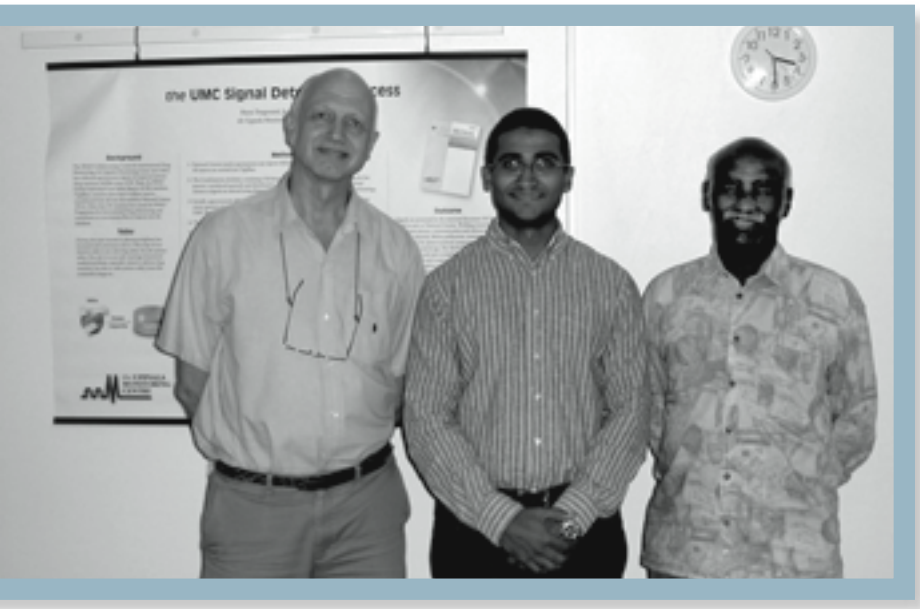
UMC Visitors

Sten Olsson

The UMC had the pleasure of receiving Mr Mohammed Solayman from Egypt, for a short visit on 20 July. Mr Solayman is an academic staff member of the Clinical Pharmacy Department, Ain Shams University, Cairo, and collaborates with the National Pharmacovigilance Centre at the Central Administration of Pharmaceutical Affairs, headed by Dr Amr Saad. Mr Solayman has taken a special interest in highlighting the concepts of pharmacovigilance among Egyptian pharmacy students. During his visit we discussed the requirements for reporting of ICSRs to the UMC and options for development support for the young Egyptian centre.

Linda Härmark and Florence van Hunsel from Lareb foundation, the Netherlands, visited the UMC on 11 August. They have accepted an assignment on behalf of the Monitoring Medicines project (see page 11) to review existing national programmes for reporting of ICSRs directly from the public. Their findings will form the basis for the further development of guidelines and systems for public reporting within the Monitoring Medicines project. Their results will also be presented at the annual meeting of National Centres in Accra, Ghana.

Linda Härmark and Florence van Hunsel (Lareb)



Sten Olsson, Mohammed Solayman and Mohamed Farah

DATES	TITLE	PLACE	ORGANISER/CONTACT
29-31 October 2010	5th Asian Conference on Pharmacoepidemiology	Tokyo, Japan	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
3 November 2010	Introduction to Signal Detection and Data Mining	Horsham, PA, USA	DIA Tel: +1-215-442-6158 E-mail: Ellen.Diegel@diahome.org
3-4 November 2010	Corso base di Farmacovigilanza 2010	Milano, Italy	EasyB Srl Tel: +39 (0)35 0347169 E-mail: enrico.pedroni@easy-b.it ; www.easy-b.it
3-6 November 2010	10th ISoP Annual Meeting: 'Pharmacovigilance in the Global Village' (Training courses on 7 November)	Accra, Ghana	International Society of Pharmacovigilance www.isop2010.org
10-11 November 2010	Case Narrative Writing for Reporting Adverse Events	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
24-25 November 2010	Pharmacovigilance in products subject to licensing agreements	London, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
26 November 2010	ENCePP Information Day	London, UK	DIA Europe Tel: +41 61 225 51 42 E-mail: Michael.Hediger@diaeurope.org
26-28 November 2010	Pharmacovigilance System and Rational Use of Drugs: An Integrated Approach (SoPI 10th Annual Conference)	New Delhi, India	Society of Pharmacovigilance (India) Tel: +91 (0)11-23741723 E-mail: isrpt2008@gmail.com
29-30 November 2010	MedDRA and pharmacovigilance – London, UK	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
1-3 December 2010	Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing	Paris, France	DIA Europe Tel: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
2-3 December 2010	Advanced Workshop on Pharmacovigilance Planning and Risk Management	Fareham, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
13-15 December 2010	Pharmacovigilance – A basic course for those working in the EU, USA and Japan	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
13-16 December 2010	Pharmacology Havana 2010, including 5th Workshop on Pharmacovigilance	Havana, Cuba	Cuban Society of Pharmacology Tel: +53 7 271 8331 Fax: +53 7 272 0653 www.pharmacologyhavana.com
26-28 January 2011	Medical Aspects of Adverse Drug Reactions	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
9-11 April 2011	ISPE Mid-Year Meeting	Florence, Italy	ISPE www.pharmacoepi.org/meetings/ E-mail: ISPE@paimgmt.com
2-13 May 2011	The UMC course 'Pharmacovigilance – the Study of Adverse Drug Reactions and Related Problems'	Uppsala, Sweden	UMC Tel: +46 (0)18 65 60 60 E-mail: info@who-umc.org www.who-umc.org > Promotion & Training
18-19 May 2011	Keeping up with the constantly-changing regulatory environment for pharmacovigilance	London, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/

the UPPSALA MONITORING CENTRE

The Uppsala Monitoring Centre (*the* UMC) is the field-name of the WHO Collaborating Centre for International Drug Monitoring, responsible for the operational management of the WHO Programme for International Drug Monitoring.

An independent centre of scientific excellence, *the* UMC offers products and services, derived from the WHO global ICSR database, VigiBase™ reported from member countries of the WHO Programme.

With an independent and global perspective on drug safety, *the* UMC provides resources for regulatory agencies, health professionals, researchers and the pharmaceutical industry.

The UMC's important worldwide work is financed solely by the organisation itself, without support from WHO, the Swedish Government, member countries of the WHO Programme or any grant-making body.

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